IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,	)	
Plaintiffs,	)	C.A. No. 18-823-CFC
v.	)	**PUBLIC VERSION**
EAGLE PHARMACEUTICALS INC.,	)	
Defendant.	)	

EAGLE'S CONCISE STATEMENT OF FACTS IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT

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Pursuant to the Court's April 9, 2020 Order and Form Scheduling Order, Defendant Eagle Pharmaceuticals Inc. ("Eagle") submits the following Concise Statement of Facts in support of its request to file a motion for summary judgment of non-infringement:

TABLE OF EXHIBITS[1]

Ex. No.	Description
1.	Approval Letter for NDA No. 204485 (PAR-VASO_0015573–586) (Excerpts)
2.	Approval Letter for NDA No. 204485/S-003 (PAR-VASO_0014542–547) (Excerpts)
3.	Mar. 17, 2020 E-mail from Brian Goldberg to Ashley Cade
4.	U.S. Patent No. 9,687,526 (PAR-VASO_0295299–377)[2]
5.	U.S. Patent No. 9,744,209 (PAR-VASO_0295216–298)
6.	U.S. Patent No. 9,750,785 (PAR-VASO_0295378–459)
7.	Sept. 6, 2019 E-mail from Sharon Gagliardi to Christopher Citro
8.	Plaintiffs' Second Supplemental Objections and Responses to Eagle Pharmaceuticals Inc.'s First Set of Interrogatories (Nos. 4-10, 12-13) (Excerpts)
9.	Paragraph IV Acknowledgement ANDA Receipt Letter for ANDA No. 211538 (EAGLEVAS0000013–018) (Excerpts)
10.	Module 1.12.12 Comparison of Generic Drug and RLD for ANDA No. 211538 (EAGLEVAS0000076–077)
11.	Highlights of Prescribing Information for VASOPRESSIN INJECTION for ANDA No. 211538 (EAGLEVAS0043566–568)
12.	Module 2 Supplement: Question-based Review for Drug Product for ANDA No. 211538 (EAGLEVAS0043670–790) (Excerpts)
13.	Approval Letter for NDA No. 204485/S-002 (PAR-VASO_0014782–787) (Excerpts)

[1] Exhibits are attached to the Declaration of Ashley Cade.

[2] Due to volume, relevant excerpts of the Patents-in-Suit have been provided. Full copies can be found at D.I. 1, Exs. B, C, E.

Ex. No.	Description
14.	Module 3.2.P.5.1 Specifications for ANDA No. 211538 [redacted] (EAGLEVAS0046173–175) (Excerpts)
15.	Module 3.2.P.5.1 Specifications for ANDA No. 211538 [redacted] (EAGLEVAS0001328–29)
16.	Module 3.2.P.8.1 Stability Summary and Conclusion for ANDA No. 111538 (EAGLEVAS0047328–355) (Excerpts)
17.	Module 3.2.P.3.3 Description of Manufacturing Process and Process Controls for ANDA No. 211538 (EAGLEVAS0045476–508) (Excerpts)
18.	Executed Batch Record [redacted] for ANDA No. 211538 (EAGLEVAS0001921–2327) (Excerpts)
19.	Compilation of Stability Data [redacted] for ANDA No. 211538 (EAGLEVAS0047274–303) (Excerpts)
20.	[redacted] (AMRIVAS0114545)
21.	Opening Expert Report of Lee E. Kirsch, Ph.D. Regarding Infringement of U.S. Patent Nos. 9,687,526, 9,744,209, and 9,750,785 (Excerpts)
22.	Reply Expert Report of Lee E. Kirsch, Ph.D. Regarding Infringement (Excerpts)
23.	Compilation of Stability Data [redacted] (AMRIVAS0117140–147, 0117152–159, 0117162–169) (Excerpts)
24.	Letter from Eagle Pharmaceuticals to Office of Generic Drugs (HFD-600), FDA, enclosing [redacted] ANDA No. 211538 (EAGLEVAS0043614–63) (Excerpts)
25.	Executed Batch Record [redacted] for ANDA No. 211548 (EAGLEVAS0047362–8071) (Excerpts)
26.	Executed Batch Record [redacted] for ANDA No. 211548 (EAGLEVAS0048072–666) (Excerpts)
27.	Executed Batch Record [redacted] for ANDA No. 211548 (EAGLEVAS0048667–9378) (Excerpts)
28.	Compilation of Stability Data [redacted] (AMRIVAS0117110–17, 0117120–27, 0117130–37) (Excerpts)

Ex. No.	Description
29.	Proposed Commercial Batch Record for Vasopressin Injection, USP for ANDA No. 211538 (EAGLEVAS0045509–605) (Excerpts)
30.	Module 3.2.P.3.4 Control of Critical Steps and Intermediate for ANDA No. 211538 (EAGLEVAS0045429–443) (Excerpts)

I. PAR'S VASOSTRICT® PRODUCT

1. In April 2014, Par received FDA approval for its original Vasostrict® product, which was made with a pH of 3.4–3.6. (Ex. 1 at PAR-VASO_0015573, 581, 586.)

2. In March 2016, Par received FDA approval for a reformulated Vasostrict® product, which is made with a pH of 3.8. (Ex. 2 at PAR-VASO_0014542–43, 545.)

II. THE PATENTS-IN-SUIT

3. For purposes of trial, Par asserts that Eagle's ANDA product will literally infringe claim 13 of U.S. Patent No. 9,687,526 ("'526 Patent"); claims 1, 3–5, and 7 of U.S. Patent No. 9,744,209 ("'209 Patent"); and claims 1, 4, 5, and 8 of U.S. Patent No. 9,750,785 ("'785 Patent") ("Patents-in-Suit"). (Ex. 3.)

4. Claim 13 of the '526 patent requires a vasopressin formulation having a pH of 3.8. (Ex. 4, claims 1, 13.)

5. Each asserted claim of the '209 and '785 patents requires a vasopressin formulation having a pH of 3.7–3.9. (Ex. 5, claim 1; Ex. 6, claim 1.)

6. Par contends that the Patents-in-Suit cover reformulated Vasostrict®, but not original Vasostrict®. (Ex. 7; Ex. 8.)

III. THE ANDA PROCESS

7. The Hatch-Waxman Act allows for the filing of an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of an

approved drug product, without separately establishing safety and efficacy. 21 U.S.C. § 355(j).

8. If a proposed generic product is rated "Q1/Q2" to an approved product, the FDA has determined that it is qualitatively and quantitatively the same as the approved product, and will not require separate bioequivalence studies. 21 CFR § 320.22(b)(1); *see also id.* § 314.94(a)(9)(iii).

9. The ANDA specifies the formulation and properties of the proposed generic product that will be marketed by the applicant, and provides specifications for parameters such as pH and impurities in accordance with good manufacturing practices. *Id.* § 314.94(a)(5)–(7), (9); *see also* § 314.50(d)(1)(i)–(ii); *see generally* 21 CFR § 211 *et seq*. (Current Good Manufacturing Practices For Finished Pharmaceuticals).

10. Manufacturing specifications define properties the product must have during specific steps in the manufacturing process. *Id.* § 211.110(a)–(c). "Release" specifications define properties the product must have on release from manufacturing. *Id.* § 211.165(a), (c)–(f). "Stability" specifications define properties the product must have after release and through its shelf life. *Id.* § 211.166(a).

11. An ANDA applicant must conduct stability studies demonstrating that its proposed ANDA product will meet its specifications over its shelf life. *Id.* § 211.166. In such studies, the product may be stored under various conditions and

appropriate measurements taken at regular intervals during the product's shelf life, which are reported to the FDA. *Id.* § 211.166(b).

12. Once its ANDA is approved, a generic manufacturer may not market a product that does not comply with its ANDA specifications, without being subject to strict sanctions. *See, e.g.*, 21 U.S.C. §§ 331(d), 332(a), 333(a), 334(a)(1), 335b(a)(1), 335c(a)(1).

IV. EAGLE'S ANDA PRODUCT

A. Background

13. On March 23, 2018, Eagle's ANDA No. 211538 was accepted for filing by the FDA. (Ex. 9 at EAGLEVAS0000013.) [redacted]

B. Eagle's ANDA pH Specifications

16. [redacted]

C. Stability Testing of Eagle's ANDA Product

18. With its ANDA, Eagle was required to submit results of stability testing of samples of its ANDA product to the FDA. 21 CFR § 211.166.

19. [redacted]

1. [redacted]

21. [redacted]

27. [redacted]

32. [redacted]

[redacted] [redacted]

2. [redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

3. [redacted]

[redacted] [redacted]

38. [redacted]

4. [redacted]

43. [redacted]

Respectfully submitted,

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